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Taiwan

Biotechnology

Taiwan Implements Stacks Registration

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Report Highlights:

Taiwan has implemented registration for stacked traits, effective immediately, in accordance with a May 6 notice issued by the Department of Health (DOH). Taiwan believes that this is supplementary to existing GM registration requirements on single events. While it does not intend to make a notification to the WTO, DOH is open to suggestions from interested parties. DOH did not specify a deadline for completion of commercial stacked event registration. As a result, no impact on US corn and soybean trade is anticipated.

Includes PSD Changes: No
Includes Trade Matrix: No
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Summary

Taiwan has implemented registration for stacked traits, effective immediately, in accordance with a May 6 notice issued by the Department of Health (DOH). Taiwan believes that this is supplementary to existing GM registration requirements on single events, and does not intend to make a notification to the WTO. DOH also did not specify a deadline for completion of commercial stacked event registration. As a result, no impact on US corn and soybean trade is anticipated due to Taiwan's implementation of stacked event registration.

According to the following Guideline for Food Assessment of Foods Derived from Genetically Modified Plants with Stacked Traits, commercial stacked events belong to Category I and II are allowed to submit a simplified dossier for DOH's approval registration review, however, Category III stacked events will be treated as brand new events that require submission of a comprehensive dossier for full review. According to DOH's investigation, there are some twenty commercial stacked corn events on the Taiwan market, one of which falls into Category II, and the rest are Category I. There are no soybean stacked events commercialized.

DOH is open to suggestions from interested parties to improve Taiwan's stacked event registration process. The following English version of the Guideline is not yet published on the DOH website.

Guideline for food safety assessment of foods derived from genetically modified plants with stacked traits

I. Food safety assessment of foods derived from genetically modified plants with stacked traits

This Guideline applies only to foods produced using genetically modified plants with stacked traits obtained through conventional breeding between genetically modified plants that are already approved.

II. Classification of genetically modified plants with stacked traits:

A) Category I: plants with two or more traits that are unrelated.
B) Category II: plants with two or more traits that are related but with different modes of action.
C) Category III: plants with two or more traits that function in the same biosynthetic pathway (i.e., have increased potential for interaction).

III. Food safety assessment of foods derived from genetically modified plants with stacked traits belonging to category I and II

The following bridging studies would need to be carried out to confirm that the stacked product is derived from the combination by traditional breeding of the single genetically modified events. The bridging studies would consist of
molecular characterization: a fingerprint-type Southern blot analysis, in comparison to the parental lines; information on the expression of new proteins: analysis of gene expression in the stacked product to confirm that gene expression in relevant tissue(s) is comparable to

that in the single genetically modified events; and compositional analysis and agronomic variables: the compositional and agronomic analysis for the stacked product would be undertaken over a single growing season (4 sites), and relevant comparisons would be made either with the single-event genetically modified plants or with the non- genetically modified control of comparable genetic background.

Protein safety evaluation and animal feeding studies of foods derived from genetically modified plants with stacked traits belonging to category I and II would need to be conducted when necessary.

If no changes to protein mode of action can be expected in the stacked product, no additional safety evaluation of the proteins and animal feeding studies would be required. If an interaction between the introduced proteins affecting their mode of action is expected, the need for additional studies should be evaluated on a case-by-case basis.

IV. Foods derived from genetically modified plants with stacked traits belonging to category III are considered as new genetically modified foods, requiring a complete food safety assessment carried out in accordance with DOH guidelines.

V. Review process

Recognizing the rapid pace of development in the field of biotechnology, the approach to food safety assessment of foods derived from modern biotechnology should be reviewed when necessary to ensure that emerging scientific information is incorporated into the risk analysis. When new scientific information relevant to a risk assessment becomes available the assessment should be reviewed to incorporate that information and, if necessary, risk management measures adapted accordingly.